

K082117

FEB 18 2009

MAQUET

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter: Maquet Cardiopulmonary AG
Hechinger Strasse 38
72145 Hirrlingen
Germany

Contact Person: Katrin Schwenkglenks
Phone: +49 7478 921-151
Fax: +49 7478 921-400
E-mail: katrin.schwenkglenks@maquet-cp.com

Date Prepared: July 18, 2008

Device Trade Name: Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating

Common/Usual name: Oxygenator with integrated heat exchanger and optional integrated arterial filter

Classification names: Oxygenator, cardiopulmonary bypass
Heat Exchanger, cardiopulmonary bypass
Filter, blood, cardiopulmonary bypass, arterial line

Predicate Devices: Quadrox Hollow Fiber Membrane Oxygenator with Safeline Coating (art.code HMO 2030), K030264, Quartz Arterial Filter (art.code HBF 140), K001787 by Maquet Cardiopulmonary AG and Synthesis Ph.I.S.I.O. Adult Membrane Oxygenator With Integrated Arterial Filter with Ph.I.S.I.O. Coating by Sorin Group Italia S.r.l., K073380.

Device Description:

The Quadrox-i Adult is a blood-gas exchanger with integrated heat exchanger and optionally integrated arterial blood filter. The Quadrox-i Adult may be marketed both as single product and pre-mounted with the venous hardshell cardiotomy reservoir (K003551, K982136).

Indications for Use:

The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The Quadrox-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

The oxygenator is suitable for the delivery of the volatile anesthetics isoflurane and sevoflurane. The anesthetic gas is administered through the oxygenator's gas inlet by means of a suitable anesthetic gas vaporizer. Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Statement of Technical Comparison:

The Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating is well comparable to the Quadrox Hollow Fiber Membrane Oxygenator with Safeline Coating regarding the intended use, design, principals of operation, biocompatibility and performance as related to the oxygenator and heat exchanger part, as well as to the Quart Arterial Filter as related to the filter part. The Softline Coating is a biopassive coating comparable to other coatings on the market, as e.g. the Ph.I.S.I.O. Coating by the Sorin Group Italia S.r.l.

Non-clinical Testing:

The Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating has been tested to and met the requirements of ISO 10993-1 Biologic Evaluation of Medical Devices as well as the requirements of ISO 7199: 1996 "Cardiovascular implants and artificial organs – blood gas exchangers (oxygenators) as well as the requirements of ISO 15675: 2001 "Cardiovascular implants and artificial organs – Cardiopulmonary Bypass – Arterial line blood filters".

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Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating described in this submission is substantially equivalent to the Quadrox Hollow Fiber Membrane Oxygenator with Safeline Coating as well as to the Quart Arterial Filter with regards to the filter function.

The following areas have been tested:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating is substantially equivalent to the named predicate devices which currently hold market clearance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

FEB 18 2009

Re: K082117

Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating

Regulation Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary bypass oxygenator

Regulatory Class: Class II (two)

Product Code: DTZ

Dated: February 12, 2009

Received: February 17, 2009

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Katrin Schwenkglenks

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman

 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082117

Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating

Indications for Use:

The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 7 l/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The Quadrox-i Adult (HMO 71000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm. The device's utilization period is limited to six hours.

The oxygenator is suitable for the delivery of the volatile anesthetics isoflurane and sevoflurane. The anesthetic gas is administered through the oxygenator's gas inlet by means of a suitable anesthetic gas vaporizer.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bohner
(Division Sign-Off)
Division of Cardiovascular Devices

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(Posted November 13, 2003)